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REMARKS

Pursuant to the Final Office Action dated February 8, 2007, all pending claims, namely claims 1-7, 10-22, 33, 34, 45 and 48-63, stand rejected. By this Amendment and Response, claims 1, 11, 12, 45 and 55 have been amended. All claims are believed to be in allowable form and present allowable subject matter.

Amendments to the Claims

Claims 1, 11, 12, 45 and 55 have been amended to improve the clarity of the same. Specifically, independent claims 1, 45 and 55 have been amended to make clear that the hydrophilic polymers are "water absorbing, water vapor absorbing and wettable" consistent with the text of the application as filed as found at page 8, lines 2-3. These claims have also been amended from an editorial perspective to leave no doubt that the high aspect ratio antimicrobial additive is in the form of discrete microparticles of the hydrophilic polymer having dispersed therein the inorganic antimicrobial agent wherein these microparticles are of the claimed particle size and aspect ratio.

Finally, claims 11 and 12 have been amended to leave no doubt that the polyurethane employable in the practice of the present invention is a hydrophilic polyurethane. This clarification is inherent from the application as a whole and is also expressly supported at page 15, lines 1-3, of the application as filed.

None of the amendments present new matter and, thus, all such amendments should be entered.

Anticipation in view of Hagiwara et. al. (US 4,775,585 – "Hagiwara")

Claims 1-4, 10-12, 22, 33, 34, 48 and 49 remain rejected under 35 USC 102(b) as being anticipated by Hagiwara. It is alleged that Hagiwara teaches a polymer article having antibacterial properties as well as a physical properties similar to those of the polymer itself which contain antimicrobial zeolite particles and wherein the polymer can be highly hydrophilic. It is stated that the particle size of the zeolite can be selected depending upon the application and may be in the range of a few microns to tens of microns or even above several hundred microns. It is also noted that Hagiwara teaches the preparation of fiber or yarns of the antimicrobial polymer which inherently have an aspect ratio of greater than 2 and which may "be mix spun,

mix woven, cross woven or union knitted with fibers or yarns having no metal-zeolite to give an antibacterial fiber article...." (Col. 10, lines 11-16). Finally, it is also alleged that the polyurethane of Hagiwara inherently possesses a water absorption at equilibrium of at least about 20% by weight.

In responding to Applicants' prior arguments rebutting the foregoing grounds of rejection, the examiner states that "claim 1 does not recite any microparticle polymer, it only describes 'an antimicrobial additive being in the form of a microparticle.'" It is further stated that the antimicrobial in claim 1 is the inorganic particles while the polymer is not recited as being in microparticle form. Relative to Applicants' prior argument of non-enablement of Hagiwara, it is stated that claim 1 does not recite a 'polymer composition." Finally, it is stated that "Hagiwara suggested the use of polyurethane which is the same hydrophilic polymer recited in the instant claims." In following, it is alleged that since it uses the same polymer it would inherently have the same characteristics.

By the foregoing amendments Applicants have hopefully made clear that indeed the claimed high aspect ratio antimicrobial additives of independent claims 1 and 55 and as employed in independent claim 55 are discrete hydrophilic polymer microparticles having dispersed therein the inorganic antimicrobial agent, which, quite obviously, are themselves even smaller particles. These hydrophilic polymer particles containing the inorganic antimicrobial agent, because of their claimed small size, are then capable of incorporation into other polymers and like compositions for imparting improved antimicrobial performance as compared to the neat inorganic antimicrobial agent, as employed in Hagiwara. And, while Hagiwara does include a reference to polyurethane elastomers and urethane resins, no suggestion is made that they are or could be hydrophilic. Indeed, the discussion of the impact of the use of hydrophilic polymers is far removed from the listing of suitable polymers and no connection or tie is present to suggest or infer which of the listed polymers are or could be hydrophilic or, more specifically, that a hydrophilic polyurethane was contemplated let alone suggested.

As set forth in MPEP 2112, in order to establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however,

may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." In re Robertson, 169 F3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex Parte Levy, 17 USPQ2d 1461, 1464 (Bd Pat App & Inter 1990).

In the instant application, the examiner has merely concluded that a polyurethane is a polyurethane and, hence, what characteristics are described in one must inherently be present in the other. However, such is not the case. As known to those skilled in the art, most all polyurethanes are hydrophobic materials, having no to little hydrophilic characteristics. Hydrophilic polyurethanes as defined by and employed in the practice of the present invention represent but a small, specialty subset of the family of polyurethanes. Typically, hydrophilic polyurethanes are prepared by either blending a hydrophilic polymer with a conventional polyurethane or by copolymerizing hydrophlic polymer segments into a polyurethane, as taught in, e.g., Marans et. al. (US 4,403,083) and Fischer et. al. (US 6,399,735). Thus, Hagiwara neither explicitly nor inherently discloses hydrophilic polyurethanes, let alone ones that are water absorbing, water vapor absorbing and wettable and have a water absorption at equilibrium of at least 5 weight percent, as required by the claims of the present application.

As is well established in Patent Law, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference" *Verdegall Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed, Circ. 1987). "The identical invention must be shown in as complete detail as is contained in the...claims." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Contrary to the assertion of the Patent Office, as discussed above and in the prior response, no such findings are present in Hagiwara. Specifically, Hagiwara does not disclose, explicitly or inherently, discrete microparticles of a hydrophilic polymer having an aspect ratio of greater than about 2, whose largest dimension is from about 50 to about 500 microns, wherein the hydrophilic polymer i) has dispersed or incorporated therein a plurality of particles of an inorganic antimicrobial agent; ii) is water absorbing, water vapor absorbing and wettable; and

iii) has a water absorption at equilibrium of at least 5 weight percent. Consequently, no anticipation is found and the anticipation rejection of claims 1-4, 10-12, 22, 33, 34, 48 and 49 should be withdrawn and the claims passed on to allowance.

Obviousness in over Hagiwara et. al. (US 4,775,585 – "Hagiwara") in view of Trogolo et. al. (US 6,436,422 – "Trogolo"), Gibson et. al. (US 6,413,536 – "Gibson") and further in view of Michal et. al. (US 6,287,285 – "Michal")

Claims 1-7, 10-22, 33, 34, 45, 48-51 and 53-63 remain rejected under 35 USC 103(a) as being unpatentable over Hagiwara in view of Trogolo, Gibson, and further in view of Michal, for the reasons of record and as recited at pages 4 through 19 of the Final Office Action of February 8, 2007.

While Applicants are most appreciative and respectful of the detailed and explicit arguments presented by the examiner in maintaining the rejections and in endeavoring to rebut Applicants' counter arguments set forth in their response of November 10, 2006, a detailed rebuttal will be deferred as a review of the examiner's arguments suggest a misunderstanding of the very premise and elements of Applicants' invention. This is clear from the above discussion relating to the anticipation rejection over Hagiwara as well as the rebuttal arguments relative to the obviousness rejections. For example, as noted above, the examiner has presumed that the claimed antimicrobial additive is the inorganic antimicrobial agent, not, as discussed above, the hydrophilic particles having incorporated therein the inorganic antimicrobial agent. Further, in addressing Applicants' claimed particle size limitations the examiner repeatedly refers to those sections of Hagiwara pertaining to the particle size of the antimicrobial agent **NOT** the size of polymer particles comprising the hydrophilic polymer having dispersed therein the inorganic antimicrobial agent. Similarly, discussion is made repeatedly to the dispersion of the antimicrobial inorganic particles in the polymers of Hagiwara and Trogolo and of the ion release attained thereby and the utility thereof in molding applications and coating application, respectively. HOWEVER, this is not what Applicants are doing. Applicants have found that by incorporating the inorganic antimicrobial agents, including those used in Hagiwara and Trogolo, into a hydrophilic polymer and then converting that modified polymer into discrete particles having an aspect ratio of greater than about 2 and a maximum dimension of 500 microns, one

can then substitute those antimicrobial hydrophilic polymer particles for the inorganic agent of, e.g., Hagiwara and Trogolo, and attain improved performance and/or properties thereby at generally reduced cost.

In light of the examiner's apparent confusion, perhaps it is worthwhile looking at the two references and the claimed invention by way of an analogy wherein the inorganic antimicrobial agent is chocolate chips and the polymer, the hydrophilic polymer in the case of the claimed invention, is dough; however, unlike actual chocolate chips, the chips here are solid and non-pliable and release a chocolate odor when the chip is exposed to the atmosphere or when the dough is of a type that allows for the odor to pass through the dough (a hydrophilic dough). All three incorporate the chocolate chips into the dough, but do so in different configurations for different reasons and, thereby attain different results. Specifically,...

Hagiwara forms a moldable dough from which molded shapes and fibers can be produced. When the chocolate chips are incorporated into the dough and the dough is subsequently shaped, there will be chocolate chips at the surface of and within the body of the shaped dough. Where the dough is in the form of a film or fiber, because such films and fibers and films are thin, it is necessary to employ smaller chocolate chips. Otherwise the die head from which the mixture is extruded will become blocked by the larger chocolate chips that cannot pass through the smaller orifice. In films, the same concern arises or, if the film is formed by compression, the larger chips will not allow the proper closing of the mold; thus, again, interfering with the formation of a film. Thus, in following with Hagiwara, particle size of the chips is contingent upon the use of the chocolate chip dough.

Hagiwara also allows for doughs that are hydrophilic or hydrophobic. With highly hydrophilic dough, Hagiwara indicates that the chocolate odor of those chocolate chips within the bulk of the dough will still be released since they are able to move through the dough. However, if the dough is hydrophobic, the odor of the chocolate chips within the bulk of the dough is trapped and cannot be released. Thus, those chips are ineffective for odor release and all chocolate odor arising from the dough is released by those chocolate chips at the surface thereof. Thus, the chocolate chips within the dough are wasted. On the other hand, while the hydrophilic doughs will release more odor for a given amount of chips added, they will also have poorer physical

properties. In this respect, assimilate the hydrophilic dough to that of a soft chocolate chip cookie and the hydrophobic dough to that of a crunchy chocolate chip cookie. The former has poor strength and physical properties whereas the latter has good strength and physical properties. Consequently, under Hagiwara, the hydrophilic dough produces a cookie of poor physical properties but more chocolate odor whereas the hydrophobic dough produces a crunchy, not easily broken cookie of less chocolate odor. By necessity, one trades odor for strength. The same holds true for antimicrobial hydrophilic and hydrophobic polymers where one trades antimicrobial performance for physical properties.

Continuing with the chocolate chip dough analogy, Trogolo forms coating compositions which would correspond to a watered down dough mixture. Trogolo applies this coating to a substrate, a second (hydrophobic) molded dough, to provide a substrate whose surface has a chocolate chip dough surface. The chocolate chips will appear at the surface and, depending upon the thickness of the coating and the size of the chips, within the matrix of the coating, but will not be present at or within the second dough to which it is applied. By employing this method, Trogolo achieves a molded dough of good strength and other physical properties while also having a strong chocolate odor release capability. Like Hagiwara, the hydrophilic dough does impart lesser physical properties to the coated molded second dough; however, here, the poor physical properties are confined to the surface coating and do not affect the underlying second dough. In this respect, if the coated molded second dough were then baked, one would have a rigid inner cookie with an outer surface layer that is easily worn away or eroded. Thus, Trogolo overcomes the compromise of Hagiwara who trades overall strength for improved chocolate odor release by restricting its compromise to the surface properties. In the polymer art, Trogolo preserves the underlying strength and properties of the substrate while still providing an outward antimicrobial surface coating or layer that has lesser physical properties. (In the last response, the undersigned referred to this coating as a film, like a paint forms a film of a coating on a wall. It was not to be construed that Trogolo formed free standing films like food wrap.)

Finally, again in keeping with the chocolate chip dough analogy, Applicants, on the other hand, produce a very specific hydrophilic chocolate chip dough and subdivide that dough into high aspect ratio microparticles which are then to be used as additives for a second dough: i.e., mini

chocolate chip cookies within a larger plain cookie. Unlike Hagiwara, they do not mold shapes or spin fibers of the chocolate chip cookie dough and, unlike Trogolo, the do not form solid coating materials to be applied to the surface of a second dough. As with the chocolate chips of Hagiwara, Applicants chocolate chip dough particles will be at the surface and within the bulk of the second dough. As discussed below in reference to the attached Declaration of Jeffrey A. Trogolo, by increasing the size of the chocolate chip dough particle, one increases the likelihood that a particle will be at the surface of the second dough into which it is incorporated so as to allow for chocolate odor release. And, since the chocolate chips of Applicants' invention are in a hydrophilic dough, even those chips removed from the surface of the chocolate chip dough particles will participate in the release of the chocolate odor so long as the chocolate chip dough particle is at the surface. Thus, each chocolate chip dough particle of the present invention serves as a reservoir of a large amount of chocolate odor since all the chocolate chips in the particle are able to release their odor. This contrasts sharply with Hagiwara where, when the dough is hydrophobic, none of the chocolate chips removed from the surface will participate in odor release. Furthermore, as noted above, since these chocolate chip dough particles have a higher probability of being at the surface of the second dough than if the chips incorporated therein were individually added to the second dough, more chocolate odor is released for less chocolate chips. Additionally, since one is able to use less chocolate chips for the same odor release, the impact of these particles of chocolate chip dough on the overall physical properties and/or characteristics of the second polymer is minimal. Thus, where the second dough is hydrophobic, Applicants are able to achieve far better chocolate odor release than Hagiwara without the compromise on physical properties of the surface as found with Trogolo.

In that embodiment of Applicants' invention where the second dough is also hydrophilic, one is able to control and alter the release rate of the chocolate odor from the chocolate chip dough particles from that hydrophilic polymer. Here the hydrophilic polymer of the first dough in which the chocolate chips are incorporated will control the release rate of the chocolate odor from the chips and, consequently from the second dough where the second dough is more hydrophilic.

From the polymer perspective, Applicants invention enables the production of polymer articles that have good antimicrobial performance without compromising, or with minimal impact on, the physical properties of the matrix polymer itself. Furthermore, in hydrophobic polymer matrices, Applicants are able to achieve excellent antimicrobial performance and longevity with less antimicrobial agent: thus, attaining a marked improvement from a cost/benefit or cost/effectiveness standpoint. Relative to the high aspect ratio, Applicants have also found that by increasing the particle size of their polymeric antimicrobial agents, one increases the likelihood that any given particle will be at the surface of the polymer matrix into which it is incorporated. These unexpected results are presented by way of analogy to low aspect ratio particles as set forth in the attached Declaration of Jeffrey A Trogolo. As shown in that section of the Declaration entitled "Particle Size Effect," increasing the particle size markedly improves ion release and longevity, despite the fact that the overall loading is the same. Even though fewer particles are at the surface, the particles that are at the surface have far greater volume and, hence, antimicrobial content, when the same total volume is used. As seen in Tables 1 and 2 and Figure 1 of the Declaration, this translates into much higher ion release and longevity of release: far exceeding the ion release and longevity of the neat antimicrobial agent as used in Hagiwara and Trogolo. By using a high aspect ratio particle, one is able to achieve and take advantage of this finding in those end-use applications where the polymer composition is to be formed into thin elements such as films or fibers and/or whose processing will not tolerate large, low aspect ratio particles.

Thus, while Applicants do not believe prima facie obviousness has been established, particularly in light of the apparent misunderstanding of the invention and the cited art, any such allegation is amply rebutted by the findings of unexpected results and marked improvement as found and associated with the antimicrobial agents as claimed.

For these reasons and for the reasons already of record, Applicants believe the rejections should be withdrawn and the claims passed on to allowance.

Relative to Gibson et. al., while Applicants continue to assert that this in non-analogous art, as shown in that section of the accompanying Declaration of Jeffrey A. Trogolo entitled "Hydrophilic Modification: Encapsulation v. Matrix Modification" and as discussed in greater

detail below, the mere addition of ingredients to modify the release of bioactive components does not provide the same benefit as that provided by Applicants' invention. Regardless, while it is known that one may modify the properties, including, in certain cases, the release characteristics of a given system or composition, by the use of various additives, nothing in Gibson et. al. would lead one to expect the improvement as shown by Applicants in their system.

Specifically, in the Declaration, a hydrophilic polyurethane was made by adding 20 wt% of a hydrophilic polymer (polyvinylpyrrolidone (PVP)) to a curable hydrophobic polyurethane composition and then using that composition to produce polymer particles (PU2) as well as encapsulated silver zeolite particles in accordance with the present invention (ME2). Like polymer particles (PU1) and encapsulated silver zeolite particles (ME1) were also made using the neat hydrophobic polyurethane. As seen in Table 3, the addition of the PVP clearly rendered the previously hydrophobic polyurethane sufficiently hydrophilic so as to enable the release of the metal ions (compare Example 3 with Example 5, Table 3). Indeed, surprisingly, the encapsulation of the silver zeolites with the hydrophilic polymer resulted in an 80% increase in ion release when added to a hydrophobic epoxy matrix, even as compared to the use of an equivalent amount of the neat, unencapsulated silver zeolite. In contrast, that composition wherein the hydrophilic polyurethane and the silver zeolite were each added as separate componenets to the hydrophobic epoxy matrix resulted in essentially no difference in ion release or a slightly worsened release than the use of the neat, unencapsulated silver zeolite by itself (compare Example 4 with Example 1, Table 3).

Thus, contrary to the assertion of the examiner, improved release it is not merely a matter of the addition of a polymer, whether biodegradable or non-biodegradable, or even, specifically, a hydrophilic polyurethane; rather, as shown by Applicants and the Trogolo Declaration, it is absolutely critical that the antimicrobial agent be incorporated into the hydrophilic polymer prior to its incorporation into the hydrophobic polymer. Furthermore, nothing in Gibson et. al. would have predicted the marked and unexpected improvement in ion release, even as compared to the neat antimicrobial agent, as attained by Applicant when practicing the specific combination/-orientation as claimed by Applicants.

Thus, again, in view of the unexpected and marked improved results any inference of obviousness over Trogolo and Hagiwara in view of Gibson et. al. is fully rebutted and the rejection should be withdrawn and the claims passed on to allowance.

Finally, while Applicants maintain their rebuttal arguments to the combined teachings of Michal, in it well established that claims dependent upon an allowable base or independent claim are allowable. Therefore, no further discussion is needed or warranted at this time.

Inasmuch as all claims are shown to be patentable, it is respectfully requested that the rejections be withdrawn and all claims passed on to allowance.

Claims Fees

Inasmuch as no changes have been made to the number of pending claims in the application, no additional claims fees are owed

Request for Extension of Time

By this response, Applicants hereby petition for a two-month extension of time; thereby extending the response period from May 8, 2007 to and including July 9, 2007, the first business day following July 8, 2007. Enclosed is a Credit Card Authorization in the amount of $620.00, which is inclusive of the $225.00 fee in payment for the Petition Fee under 37 CFR 1.17(a)(2).

Request for Continued Examination

Accompanying this Amendment and Response is a Request for Continued Examination under 37 CFR 1.114 for purposes of removing the finality of the rejection and ensuring entry of this Amendment and Response for appeal, if necessary. The above-referenced enclosed Credit Card Authorization also includes the amount of $395.00 as payment for the associated fee under 37 CFR 1.17(e).

Conclusion

In light of the foregoing remarks, Applicants reaffirm their belief that the claims as presented are clearly patentable over the art. The Examiner is requested to also review the prior response which concisely sets forth a detailed explanation of the various elements and embodiments of the claimed invention. Despite the many allegations and conclusions of the

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Examiner, Applicants have fully rebutted the arguments presented. None of the art, alone or in combination, provides any objective basis or motivation to prepare the narrowly defined high aspect ratio microparticles claimed nor any inference or suggestion that those particles could be used as a polymer additive for imparting improved antimicrobial performance to a polymer matrix as compared a similar polymer matrix where the same amount, if not a lesser amount, of antimicrobial agent is added in its neat form. Thus, Applicants respectfully request that the rejections be withdrawn and the application be passed on to allowance.

Respectfully submitted,

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Increasing the particle size correspondingly increased the likelihood that any given particle would be in contact with the surface of the polymer into which it is incorporated. This is illustrated in Figure 1 which shows the cross-sections of two molded plastic parts containing the same loading of two different additives, one of a large particle size and the other of a smaller particle size. In the illustration, the combined area of the two dimensional particles (circles) in the top material is equal to that in the bottom material, which serves as an analogy to the three dimensional case of equal loading, but different particle size.

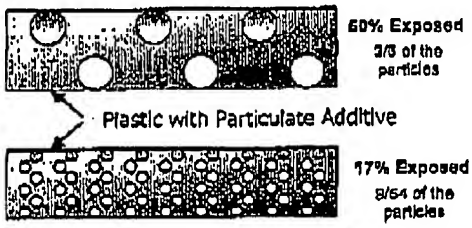

Figure 1

From the illustration it is apparent that a greater percentage (50%) of the larger particles added to the plastic are in contact with the surface as opposed to only 17% for the smaller particles, despite the same loading. Although this illustration depicts particles of a unitary aspect ratio (1:1), the same effect would be seen with high aspect ratio particles: though to a somewhat lesser extent since a portion of those particles would be oriented so that the larger dimension is coplanar with the surface and not intersecting or touching the surface.

Relative to the antimicrobial particles of the present invention, since the concentration of the antimicrobial agent in the hydrophilic polymer from which the particulate additives of Figure 1 are made is the same, the larger particles posses a proportionately higher amount of contained antimicrobial agent. Thus, even though fewer individual particles touch the surface and, hence, participate in ion release, they still provide for a significantly larger reservoir of available antimicrobial agent. This is because in hydrophobic matrices, only those particles in contact with the surface are capable of releasing their antimicrobial agent.

As proof of this enhanced antimicrobial agent release, the following experiment was conducted. Specifically, a hydrophilic acrylic polymer encapsulated silver zeolite antimicrobial was prepared by adding 50 parts by weight of a silver zeolite antimicrobial agent (AgION AJ10D antimicrobial) to 50 parts by weight (based on the solids) of an encapsulating curable hydrophilic acrylic prepolymer mix (AEP-50 from IH Polymeric Products of Sandway, Kent, UK). The mixture was allowed to cure and the resultant polymer was found to have the zeolite particles fairly evenly distributed throughout the polymer. The polymer material was then ground and the resultant particles classified according to the following particle size ranges <53μ, 53μ to 106μ, 106μ to 212μ, and > 212μ. Five polymer formulations were prepared by dry blending 1% by weight AgION AJ10D antimicrobial zeolite, and 2% by weight of each cut of the hydrophilic acrylic polymer encapsulated antimicrobial agent in separate samples of ultra high molecular weight polyethylene powder (UHMWPE - a hydrophobic polymer) to attain a final concentration of 1% AgION AJ10D in each polymer formulation. Dry blending was performed for a sufficient period of time to ensure a substantially homogenous dispersion of the antimicrobial additive in the UHMWPE powder. Aliquots of each polymer formulation were then compression molded into a 2mm thick sheet from

which test coupons measuring approximately 5 cm x 5 cm x 2 mm thick were cut.
Four samples of each test coupon were then serially extracted in an 0.8M $NaNO_3$ test solution to determine the quantity and kinetics of silver release. Extraction was initiated by submerging each test coupon in 100 ml of the test solution. After a soak time of one or more days, the test coupon was removed and the solution tested for silver concentration using a Graphite Furnace Atomic Absorption Spectrometer (PerkinElmer AAnalyst 600). The same test coupon was then placed in a fresh 0.8M $NaNO_3$ solution and the process repeated. Those test coupons containing the AgION antimicrobial zeolite in neat form were subjected to 11 extractions over 22 days; whereas, those test coupons containing the microencapsulated antimicrobial were subjected to 25 extractions over 111 days. The quantity (μg) of silver depleted from each sample on each extraction was calculated as the product of [Ag+] (μg/L) and the test volume (L) divided by the surface area of the test coupon so as to provide a normalized silver release per square centimeter of surface area. Tables 1 and 2 present the average extraction results for the four samples, the numbers presented representing the cumulative mass density of silver released. For simplicity, the results are also presented in graph form in Figure 1, which plots the cumulative Ag mass density (ng/cm^2) vs. cumulative extraction time. The results for the particle size +106/212 cut are not shown in Figure 1 in order to avoid confusion inasmuch as an inconsistency was noted with respect to what was expected. Specifically, the results would suggest that samples/test results were reversed as between the +53/-106 cut and the +106/-212 cut through the first 20 or so extractions. Nevertheless, even if one averaged the two in order to provide results for the +53/-212 cut, it is clear that the plot would have followed a path similar to and intermediate of the plots for the +212 cut and the -53 cut.

The results shown in Tables 1 and 2 and Figure 1 demonstrate that the incorporation of a hydrophilic polymer having encapsulated therein multiple particles of an antimicrobial agent into a hydrophobic polymer matrix provides a markedly and surprisingly greater and longer-lived silver release as compared to use of an equivalent weight of the neat antimicrobial agent. Furthermore, the results set forth in Table 2 and Figure 1 demonstrate that increasing the particle size of the antimicrobial additive particles markedly improves the performance thereof even though the same amount of antimicrobial agent is present in the overall formulation. As noted above, while this particular experiment was conducted with low aspect ratio additives, similar results are expected with the high aspect ratio additive. This is of significance since not all applications allow for the use of large particle size, low aspect ratio additives. For example, as indicated in Hagiwara, the use of smaller and smaller particle size antimicrobial additives is important in the case of fibers and films. Thus, the use of our claimed high aspect ratio antimicrobial additive particles enables one to take advantage of our general findings on increased ion release and longevity with larger particle size in those applications, like fibers and films, where such larger particles sizes could not otherwise be accommodated.

Table 1 – Cumulative Ag Mass Density of the neat silver zeolite

Time (hours)	0	24	48	72	120	192	240	288	360	408	432	528
Ag Mass Density (ng/cm^2)	0	64	81	87	93	98	100	102	104	106	107	108

Table 2 – Cumulative Ag Mass Density (ng/cm2) of microencapsulted silver zeolite

Sample	Time (hours)														
Cut Size (μ)	23	46	72	144	168	216	313	333	383	552	667	694	716	813	840
<53	37	54	57	70	88	105	123	130	157	186	197	202	213	219	222
+53/-106	117	159	156	169	198	225	249	259	297	333	356	361	381	399	406
+106/-212	38	62	59	79	95	118	147	153	186	230	252	272	292	318	331
+212	145	307	338	414	460	515	592	615	665	764	813	853	873	903	926

Table 2(cont'd) – Cumulative Ag Mass Density (ng/cm2) of microencapsulted silver zeolite

Sample	Time (hours)													
Cut Size (μ)	862	977	1052	1152	1488	1537	1702	2018	2066	2160	2185	2422	2521	2662
<53	224	228	238	240	247	244	250	254	254	258	258	259	260	263
+53/-106	407	418	439	448	467	466	483	496	496	508	509	513	516	523
+106/-212	330	359	394	419	469	474	531	569	565	604	611	633	639	673
+212	919	958	988	1015	1089	1088	1137	1183	1181	1208	1216	1240	1247	1273

Hydrophilic Modification: Encapsulation v. Matrix Modification.

A second experiment was conducted to demonstrate the criticality of the physical form of the invention as claimed. In this experiment, 10 grams of a silver zeolite (AgION AJ10D antimicrobial) was thoroughly mixed into 50 grams of two curable polyurethane compositions together with 3 % by wt of aziridine cross-linker. One polyurethane was a hydrophobic polyurethane and the other an 80:20 mix (by weight) of the hydrophobic polyurethane and polyvinylpyrrolidone, both from Coatings2Go of Carlisle, MA. The incorporation of the polyvinyl pyrrolidone renders the previously hydrophobic polyurethane hydrophilic. Both resin dispersions were poured into shallow trays and placed in a 103°C oven overnight so as cure/polymerize the polyurethane. The resultant solid films were individually ground in an attritor mill and screened using a 50mesh screen to remove the larger particles (i.e., those greater than 300μ). An additional quantity of virgin (i.e., no antimicrobial agent) particles of each of the two polyurethane resins was made in the same way with the exception that no antimicrobial additive was included as well.

A series of epoxy compositions were then prepared incorporating each of the aforementioned polyurethane particles. The epoxy resin system, a hydrophobic system in its cured state, was a two-part system based on diglycidyl ether of Bisphenol A and a cycloaliphatic amine curing agent. The formulation of each epoxy composition was as set forth in Table 3. All compositions, with the exception of the control, were formulated so as contain 25% by wt. silver zeolite in the cured epoxy polymer. Dispersions of each composition were prepared by hand mixing. The substantially homogeneous dispersions were then poured into individual 2-inch diameter trays and allowed to cure overnight at room temperature. The cured epoxy samples were removed from the trays and lightly sanded with emery paper and placed in individual vials containing 40 ml of an 0.8M sodium nitrate solution. The vials were placed on a tilt agitator at room temperature and rocked for 24 hours. Thereafter, the solutions were collected and diluted 50:1 with purified water and assayed for silver using atomic absorption (AA) spectrophotometry. The results of the extraction study were as set forth in Table 3.

The results presented in Table 3 clearly demonstrate the marked and unexpected increase in silver ion release resulting from the use of an antimicrobial additive wherein the additive comprises discrete particles of a hydrophilic polymer having dispersed therein the true antimicrobial active agent. Indeed, Example 5, which embodies the invention, has nearly a 100% increase in ion release over the neat antimicrobial agent despite the fact that both contain the same amount of the same silver zeolite. Merely adding the silver zeolite together with a hydrophilic polymer as individual components to the hydrophobic matrix resin (Example 4) had essentially no effect, if not a slightly detrimental effect, on ion release despite the fact that the addition of a hydrophilic polymer to a hydrophobic polymer is a known and accepted method of increasing the hydrophilic properties of a hydrophobic polymer. The addition of hydrophobic particles having incorporated therein the silver zeolite (Example 3) and the addition of hydrophobic particles and the silver zeolite as individual components (Example 2) had no or a slightly detrimental impact on ion release as compared to the use of the neat antimicrobial agent.

These results rebut the supposed teaching and expectation of Gibson et. al., and reinforce the unexpected and marked benefit of the encapsulated antimicrobial agents of the present invention.

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Again, while this particular study did not use the high aspect ratio additives, the results hereof are directly correlative to what would have been achieved.

Table 3

Component	Control	Example 1	Example 2	Example 3	Example 4	Example 5
Epoxy resin	25	25	25	25	25	25
AJ10D		0.5	0.5		0.5	
PU1			0.5			
PU2					0.5	
ME1				1		
ME2						1
Silver Extraction						
AA reading* (ppb)	0	8.5	6.6	7.7	7.9	15.3
[Ag] in extract# (ppb)	0	425	330	385	395	765

* Atomic Absorption reading of the 50:1 diluted sample.
# Actual silver content in the extraction solution

I hereby state that all statements made herein of my knowledge are true, all statements made herein on information and belief are believed to be true and all statements made herein are made with the knowledge that whoever, in any matter within the jurisdiction of the Patent and Trademark Office, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false wiring or document knowing the same to contain any false, fictitious or fraudulent statements or entry, shall be subject to the penalties set forth under 18 USC 1001, and that violations of this paragraph may jeopardize the validity or enforceability of any patent resulting therefrom.

Respectfully submitted

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